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Lets Move It Feasibility Study to determine if a school-based intervention to increase physical activity and decrease sedentary behaviour among older adolescents is feasible and acceptable

Submission date
23/05/2014

Recruitment status
No longer recruiting

Registration date
25/06/2014

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Lack of physical activity is harmful to well-being in adolescence. This is common especially in those with lower educational level, e.g., vocational college degree, compared to those who attended high schools. Schools are promising places for interventions (implement methods) to increase physical activity, as youth spend a major part of their day there. This study aims to find out whether a program to increase physical activity and reduce sitting is acceptable and feasible to be conducted in a vocational college.

Who can participate?
Teachers with health education courses among comparable educational tracks in the participating school are enrolled in this study. The students are about 16-19 years old. The core class teachers of the four classes are invited to participate in the classroom sitting reduction programme after training.

What does the study involve?
The four classes are randomly allocated to one of two groups: control and intervention. The students in the intervention group receive a 6-hour group-based programme that aims to increase their physical activity motivation and self-regulation skills. The core class teachers of the students enrolled in the intervention group receive two 2-hour training workshops to improve their motivation and skills to reduce their students sitting in class.

What are the possible benefits and risks of participating?
Benefits are increase physical activity, well-being and reduce risks associated with inactivity. There are no risks or side effects expected from the programme.

Where is the study run from?
The programme is implemented in one of the vocational colleges in the Southern Finland.

When is the study starting and how long is it expected to run for?
The study started in April 2014 and runs until December 2014.

Who is funding the study?
Ministry of Social Affairs and Health and Ministry of Education and Culture of Finland.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
201310238

Study information

Scientific Title
Cluster-randomised controlled feasibility study of a school-based multi-level intervention to increase physical activity and decrease sedentary behaviour among older adolescents

Study objectives
The aim of the proposed study is to test the feasibility and acceptability of the intervention, to test measurement and trial procedures for a future Cluster-Randomised Controlled Trial of a

newly developed school-based behaviour change intervention amongst 15-19-year-old adolescents in vocational colleges. More specifically:
1. To determine the feasibility of conducting a definitive cluster-RCT of an intervention program to increase physical activity and reduce sedentary behaviour in vocational colleges.
2. To use data arising from differences between intervention and control arm to inform a power calculation for sample size of a definitive RCT.
3. To estimate trial recruitment (percentage of students/teachers who consent to the trial) and completion/retention rates (percentage of participants completing the trial).
4. To embed a process evaluation within the pilot trial to assess the acceptability of the intervention and trial procedures for students and teachers, with a focus on the student participants with lowest activity levels and highest body fat mass at baseline:
- Assess acceptability of recruitment, randomisation and consent procedure
- Assess acceptability and feasibility of collecting reliable and valid data on primary and secondary outcomes (acceptability of measurement instruments)
- Assess acceptability of length of intervention and intervention content and materials
- Assess appropriateness/suitability of the intervention used
- Assess barriers to attendance or use
- Assess perceived impact on well-being and potential harmful effects
- To evaluate narratives about the causal model of the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Hospital District of Helsinki and Uusimaa, The Ethics Committee for gynaecology and obstetrics, pediatrics and psychiatry

Study design
Pilot outcome assessor blinded cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Physical activity and sitting behavior

Interventions

1.Intervention / Students: The intervention focuses on changing physical activity behaviours, in a sample of vocational school students. A researcher will deliver six group sessions. Groups will include 10-20 participants. The introduction of behaviour change techniques will follow a logical pattern with a discussion of the beliefs, barriers and facilitators related to physical activity in participants lives, then goal setting, action planning and self–monitoring in subsequent sessions, followed by the introduction of subsequent techniques (e.g. feedback on the behaviour) on a weekly basis concluding with relapse prevention towards the end of the intervention. After the group sessions, consenting participants will be given short booster sessions by the researcher delivering the intervention, via email and/or by phone.
Control group (standard care plus written information on physical activity from UKK-Institute): Participants in the control group will receive a leaflet after completing baseline questionnaires.
2.Intervention / Teachers: Intervention is based on: two workshops, where teachers are motivated and trained to use different techniques to reduce students sitting during classes, a webpage and equipment provided in the classroom to enable more activity for the students. Teachers will be introduced to the behavior change techniques such as goal setting, action planning, scheduling and monitoring behavior, followed by practice of these techniques. After the first workshop teachers receive a detailed manual, to increase motivation to reduce students sitting and to rehearse their skills to use different techniques to interrupt sitting. The second workshop helps the teachers plan how to overcome potential barriers and provides further methods for sitting reduction. The teachers are provided with the chance of further individual support from the researchers.
Control group (written information): Participants in the control group will receive a leaflet informing them about the benefits of breaking sitting.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Feasibility and acceptability of study procedures and intervention materials

Secondary outcome measures
1. Physical activity (accelerometer and self-reported): baseline, 6-week follow-up, 6 month-follow-up
2. BMI: baseline and 6-month follow-up
3. Body composition: muscle mass and fat mass (Tanita bioimpedance measurement): baseline and 6-month follow-up
4. Social and psychological determinants of behavior: baseline, 6-week follow-up, 6 month-follow-up

Overall study start date
04/04/2014

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Vocational students and their core class teachers whose classes involve a large amount of sitting

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
60 students, 20 teachers

Key exclusion criteria
Students:
1. Insufficient knowledge of the Finnish language to take part in group interventions and use written materials
2. Medical conditions preventing participants from engagement in physical activities.
Teachers:
1. Mostly teaching in classrooms/workshops which do not involve sitting

Date of first enrolment
04/04/2014

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Finland

Study participating centre
Social Psychology Unit
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Sponsor information

Organisation
University of Helsinki (Finland)

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Sponsor type
Government

ROR
https://ror.org/040af2s02

Funder(s)

Funder type
Government

Funder Name
Ministry of Social Affairs and Health (Finland); ref. 201310238

Funder Name
Ministry of Education and Culture (Finland); ref. 34/626/2012

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/03/2017	17/12/2020	Yes	No